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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/550,303
Filing Date: April 14, 2000
Appellant(s): HAAB ET AL.

Pamela Sherwood
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 27 October 2006 appealing from the Office action mailed 30 March 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of Claims 33-37 under 35 U.S.C. 102 over Winkler are withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,677,195	WINKLER et al	10-1997
5,252,743	BARRETT et al	5,252,743

5,843,767	BEATTIE	12-1998
4,829,010	CHANG	05-1989
5,667,976	VAN NESS et al	09-1997

Zubay, G. Biochemistry, 3rd ed. Wm C. Brown Pub., Dubuque, Iowa, 1993, pages 964-966.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 31 and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 31, Winkler et al disclose an array of discrete polypeptides, each of which is at least 50 amino acids in length wherein the array comprises 1000 or more discrete regions of distinct polypeptides/cm^2 and have a diameter of from 20 to 200 μm (Column 17, lines 49-58) and wherein the support is a slide (Column 4, lines 23-25).

Regarding Claim 33-35, Winkler et al disclose the array wherein the polypeptides are immunological receptors e.g. antibodies or antigens (Column 6, lines 8-18).

Response to Arguments

Appellant asserts that the methods of Winkler are directed to synthesizing polymers in situ on a substrate, where only small peptides can be produced and therefore does not teach the claimed invention. Appellant cites numerous passages from the teaching of Winkler wherein in situ synthesis is discussed as evidence for the assertion. Appellant further cites a research article previously provided and discussed, the article discusses the efficiency of coupling during in situ synthesis of peptides. From this, Appellant asserts that "if a 50-mer is synthesized using the in situ method, only 0.5% of the polypeptides will have the correct sequences".

The arguments have been considered but are not found persuasive to overcome the above rejection because the claims do not require an accuracy of synthesis, any correct sequence or any homology between sequences. The claims merely require polypeptides of at least 50 amino acids positioned in discrete regions. The claims do not define the composition of the polypeptides on the microarray or within any give region. Therefore arguments regarding the "correct sequence" or "heterogeneous mixture" are not commensurate in scope with the claims.

Appellant argues that the claimed "distinct polypeptide" refers to a specific polypeptide that has been selected for deposition on the array as detailed in the specification. Appellant asserts that the method of Winkler et al cannot provide the claimed distinct polypeptide because the in situ method "always results in aggregation of polypeptides of different sequence". The arguments have been considered but not found persuasive to overcome the rejection because the claims are not limited to "a specific polypeptide" that has been "selected for deposition" as asserted. Therefore the arguments are not commensurate in scope with the claims. Furthermore, Fodor does not teach the in situ synthesis results in "aggregation of polypeptides". Therefore, the argument is not supported by factual evidence.

Appellant asserts that Winkler et al is incapable of generating the claimed product. The assertion is noted, however as cited above, Winkler et al specifically teach polymers of 50, 70, 100 or more monomers at discrete regions (Column 17, lines 49-57) and therefore anticipate the claims as written.

Claims 10, 13-15, 18, 31 and 33-35, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Barrett et al (U.S. Patent No. 5,252,743, filed 13 November 1990).

Regarding Claim 10, Barrett et al disclose a microarray of discrete polypeptides on a slide (Column 8, lines 15-20) wherein each polypeptide is at least 50 amino acids (e.g.

antibody, Abstract), wherein the microarray comprises 1000 or more discrete regions of polypeptide/cm^2 wherein the regions have a diameter or 20 to 200 um (Column 18, line 67-Column 19, line 4 and Column 19, line 66-Column 20, line 68). As cited above, the courts have stated that a product is not defined over the prior art in terms of the process of making. Because Barrett et al disclose the components of the instantly claimed product, the method of making the product does not define the product over the microarray of Barrett.

Regarding Claim 13, Barrett et al disclose the microarray wherein the polypeptides are immunological receptors (e.g. antibody, Abstract and Column 20, lines 30-40).

Regarding Claim 14, Barrett et al disclose the microarray wherein the immunological receptors are antibodies (Abstract and Column 20, lines 30-40).

Regarding Claim 15, Barrett et al disclose the microarray wherein the polypeptides are immunological receptors are antigens (Abstract, line 2).

Regarding Claim 18, Barrett et al disclose the microarray wherein the polypeptides retain their binding properties (Column 21, lines 30-63).

Regarding Claim 31, Barrett et al disclose a microarray of discrete polypeptides on a slide (Column 8, lines 15-20) wherein each polypeptide is at least 50 amino acids (e.g. antibody, Abstract), wherein the microarray comprises 1000 or more discrete regions of polypeptide/cm^2 wherein the regions have a diameter or 20 to 200 um (Column 18, line 67-Column 19, line 4 and Column 19, line 66-Column 20, line 68).

Regarding Claim 33, Barrett et al disclose the microarray wherein the polypeptides are immunological receptors (e.g. antibody, Abstract and Column 20, lines 30-40).

Regarding Claim 34, Barrett et al disclose the microarray wherein the immunological receptors are antibodies (Abstract and Column 20, lines 30-40).

Regarding Claim 35, Barrett et al disclose the microarray wherein the polypeptides are immunological receptors are antigens (Abstract, line 2).

Regarding Claim 37, Barrett et al disclose the microarray wherein the polypeptides retain their binding properties (Column 21, lines 30-63).

Response to Arguments

Appellant argues that Barrett et al fail to teach a cationic film on a solid support as claimed. The argument has been considered but is not found persuasive because the above rejected claims are not drawn to a cationic film. Claims 16 and 36 define the microarray as having a cationic film. Claims 16 and 36 are rejected and addressed below under 35 U.S.C. 103. Therefore, the arguments regarding the rejections under 35 U.S.C. 102 over Barrett et al are not commensurate in scope with the rejected claims.

Claim Rejections - 35 USC § 103

Claims 10, 13-15, 18, 31, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) in view of Chang (U.S. Patent No. 4,829,010, filed May 9 1089).

Regarding Claim 31, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a planar solid support wherein the microarray comprises 1000 or more discrete regions/cm^2 (Fig. 1, Column 5, line 66-Column 6, line 6 and Claims 1 and 15) wherein the regions have a diameter of 20 to 200 μm (Claim 7). Beattie et al also teach binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Zubay defines antibodies as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). Beattie further teaches the support is a slide (Column 11, lines 40-42) but they do not specifically teach polypeptides arrayed on a slide.

Chang teaches a similar array of discrete polypeptides, each of which is at least 50 amino acids in length (antibodies, Abstract) and wherein the array comprises at least 100

discrete regions of distinct polypeptides/cm^2 (Column 4, lines 22-34) wherein the preferred support is a slide (Column 2, lines 7-10). Chang further teaches the slide is preferred because it is light transparent (Column 2, lines 7-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the slide of Chang to the broadly defined substrate of Beattie et al to thereby provide a light-transparent support as taught by Chang (Column 2, lines 7-8) for the obvious benefit of permitting detection and analysis of reactions on the support.

Regarding Claim 33-34, Beattie teaches the microarray wherein the binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 35, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 37, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions.

Furthermore, Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

Regarding Claim 10, Beattie and Chang teach a microarray of discrete polypeptides on a planar solid support of Claim 31 as discussed above and Beattie teaches the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52).

The preceding rejection is based on judicial precedent following In re Best (195 USPQ 430) and In re Fitzgerald, 205 USPQ 594 because Beattie and Chang are silent with regard loading a polypeptide solution into an elongate capillary channel and tapping its tip onto the support to dispense the solution.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Furthermore, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

> is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, because Beattie and Chang teach the structural element of the microarray as claimed, the process of making the microarray as recited in the claim does not distinguish the microarray over that of prior art.

Regarding Claim 13-14, Beattie teaches the microarray wherein the binding reagents includes antibody-antigen binding (Column 7, lines 20-21) (Column 15) and Chang teaches the polypeptides are antibodies (Abstract).

Regarding Claim 15, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 18, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions.

Furthermore, Chang teaches the arrayed polypeptides are used to bind cells bearing antigens recognizing the immobilized antibodies (Abstract), hence the antibodies maintain their native structure.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

Response to Arguments

8. Appellant argues that Beattie does not teach the geometry of the claimed microarrays i.e. formed by deposition of between 0.002 and 2 nl on the surface of a planar solid support Appellant asserts that the substrate of Beattie is a substrate comprising a plurality of channels and therefore is not a solid planar support. The argument has been considered but is not found persuasive because Beattie et al specifically teach a slide (Column 11, lines 40-42). While the reference does create nanoporous wells within the substrate, the substrate is a slide and therefore encompassed by the claimed "slide". Furthermore, Beattie illustrate their support (Fig. 1A and 1B) which has a planar surface, the planar surface being solid between the channels and also the planar surface being provided at the bottom of surface of the wells and the top surface of the wells whereby the claimed planar solid support is provided.

Appellant argues that Beattie does not deliver fluids by tapping, but instead uses a microfluidic jet. Appellant asserts that the jet devices of Beattie operate by a different mechanism and are not expected to generate the same array on a planar surface as those produced by the present invention. Appellant further points to Example 6 of Beattie, which uses a flow-thorough, vacuum system. The arguments have been considered but are not

found persuasive because Appellant has not provided any factual evidence of the asserted difference fluid delivery or array production. Therefore, the arguments are deemed unsupported arguments of counsel.

Appellant argues that Beattie teaches away from the use of planar substrates and further asserts that Beattie does not teach a slide as cited by the Office but is clearly directed to use of a porous material having functional wells. The argument has been considered but is not found persuasive because, as cited, Beattie clearly and specifically teaches and suggests using a slide as a support (Column 11, lines 40-42). Furthermore, Appellant's arguments address above merely address the teaching of Beattie. The above rejection is based on the combination of Beattie and Chang.

Appellant asserts that one of ordinary skill in the art would not have been motivated to combine the teachings of Beattie and Chang because Beattie "specifically teach that a flat surface design is undesirable" and hence the combination is hindsight reconstruction. Appellant further asserts that one of ordinary skill would not be motivated to combine the flow-through apparatus and sprayed deposition with the pipetting device of Chang. The argument has been considered but is not found persuasive because, as stated above, Beattie specifically teach a flat planar support as claimed. Furthermore, Beattie teaches fluid deposition via "low volume syringes" and does not teach or suggest "sprayed" as asserted. Therefore, Appellant appears to be mischaracterizing the fluid deposition of Beattie. Both Beattie and Chang are drawn to similar devices of immobilized binding reagents and methods for their production, hence the art is analogous. In contrast to the asserted spraying, Beattie teaches ink jet application (Example 5) of small volume (Column 14, lines 46-48). In a similar fashion, Chang teaches small volume application using a micropipetter (Column 3, lines 42-48). Hence, the method of array production is similar. One of ordinary skill in the art would have been motivated to combine the similar teachings of the references for the reasons stated above.

Applicant further asserts that the teachings of Beattie and Chang are not reasonably combined because Beattie teaches a flow-through apparatus and Chang teaches a planar surface, the combination of which would render the flow-though device of Beattie inoperable. The argument has been considered but is not found persuasive because the claimed solid support does not defined over the flow-though planar support of Beattie. Furthermore, as cited by Appellant, Beattie teaches the starting material from which the support is made is a glass slide and Chang is cited for teaching the benefits of transparency provided by using glass slide supports to thereby motivate one of ordinary skill to use the glass slide starting material as suggested by Beattie.

Appellant asserts that it would be physically impossible to utilizing the teaching of Beattie to arrive a device produced by tapping a dispensing tip against a surface of a solid support because the surface of Beattie comprises wells. The arguments have been considered but are not found persuasive because Appellant has not provided any factual evidence of the asserted difference fluid delivery or array production. Therefore, the arguments are deemed unsupported arguments of counsel.

Claim 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) in view of Chang (U.S. Patent No. 4,829,010, issued 9 May 1989) as applied to Claim 10 above and further in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claims 16 and 36, Beattie and Chang teach the microarray comprising binding reagents deposited at defined positions on a planar solid support (Claims 1 and 15) and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column

14, lines 16-52) but they do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Beattie and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

Response to Arguments

Appellant argues that Van Ness et al does not cure the deficiencies of Beattie and Chang. The argument has been considered but is not found persuasive to overcome the above rejection for the reasons stated above regarding Beattie and Chang.

Claim 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett et al (U.S. Patent No. 5,353,743, filed 13 November 1990) in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claims 16 and 36, Barrett et al disclose a microarray of discrete polypeptides on a slide (Column 8, lines 15-20) wherein each polypeptide is at least 50 amino acids (e.g. antibody, Abstract), wherein the microarray comprises 1000 or more discrete regions of polypeptide/cm^2 wherein the regions have a diameter or 20 to 200 um (Column 18, line 67-Column 19, line 4 and Column 19, line 66-Column 20, line 68). Barrett et al do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed

invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Barrett et al and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

Response to Arguments

Appellant asserts that Barrett et al is directed to region-specific attachment of anti-ligand and therefore it would not have been obvious to combine the cationic film of Van Ness with the teaching of Barrett because it would render the support of Barrett in operable. The argument has been considered but is not found persuasive because as cited above, Van Ness et al specifically teach the coating introduces multiple functional groups thereby increasing the number of binding sites for the anti-ligand (Column 4, lines 64-67). Appellant has not provided any factual evidence that the cationic polymer of Van Ness would prevent region-specific attachment as asserted.

Appellant further asserts that Barrett fails to teach polypeptides of 50 amino acids. Appellant asserts that Barrett teaches anti-ligands of 100 Daltons to more than 1 kD. Appellant states that the average amino acid is roughly 100 Daltons and therefore the anti-ligands of Barrett **may** include monomers. The argument has been considered but is not found persuasive because Barrett specifically teaches immobilized antibodies or antigens (Abstract and Column 20, lines 41-60). Furthermore, a teaching of monomers does not exclude or negate the teaching of immobilized antibodies as provided by Barrett.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

BJ Forman, Ph.D.

BJ FORMAN, PH.D.
PRIMARY EXAMINER

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